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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,421	04/09/2004	Peter Ospyka	32469-303686	1219

42074 7590 07/10/2008

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EXAMINER

BERTRAM, ERIC D

ART UNIT

PAPER NUMBER

3766

NOTIFICATION DATE

DELIVERY MODE

07/10/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/821,421	Applicant(s) OSPYKA, PETER	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,19,21-31 and 33-65 is/are pending in the application.
- 4a) Of the above claim(s) 23,26-30 and 51-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,19,21,22,24,25,31 and 33-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's arguments filed 4/23/2008 have been fully considered but they are not persuasive. In a telephone interview on 3/18/08, the Examiner indicated that claims 18, 43 and 50 would overcome Grandjean due to the claim limitation "the distal end of the tension element being attached to the anchor." However, after revisiting and reviewing the reference, the previous rejection and the scope of the current claims, Grandjean is still found to read on the claims.

2. This is due to the fact that in paragraphs 4 and 15 of the previous Office Action, the "distal end" of the tension element 120 was defined to be the entire length of the element extending from the anchor to the needle 118. As clearly seen in figure 2 of Grandjean, this "distal end" of tension element 120 is attached to the distal end of the anchor 122. Furthermore, the "proximal end" of the tension element 120 was defined to be the entire length of the element extending from the anchor 122 to connector 102 in the same paragraphs of the previous Action. Since the claims do not preclude the "proximal end" from also being connected to the tension element (i.e., the claims do not require that only the distal end is connected to the anchor"), Grandjean is still valid.

3. Also, the "proximal end" of the tension element is always threaded completely through the pole 114 of electrode 100 (See figure 4 and Col. 3, lines 32-36 and 58-62). As a result, since electrode portion 114 is not connected to the tension element, it allows for some slideable movement along the "proximal end" (as defined above) of the tension element both towards and away from the anchor at all times, including during implantation.

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4. The 35 USC 102 and 103 rejections of claims 18, 19, 21, 22, 23, 25, 31 and 33-50 are still considered proper.

5. The Examiner apologizes for missing this interpretation during the interview conducted on 3/18/08, thus resulting in the continued prosecution of this case, and invites the applicant's to contact the Examiner upon receipt of this Office Action to further discuss the Grandjean reference.

Claim Rejections - 35 USC § 112

6. The amendment to claim 18 to overcome the 35 USC 112 rejection is acknowledged and accepted. As a result, the 35 USC 112 rejection of claims 18, 19, 21, 22, 24, 25, 31 and 33-42 has been withdrawn.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 18, 19, 21, 22, 24, 25 and 31-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 19 and 25 of copending Application No. 10/971,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application contain all of the limitations of the current independent claims in addition to many others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 18, 19, 21, 22, 24, 25 and 31-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 23 and 24 of copending Application No. 10/971,549. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application contain all of the limitations of the current independent claims in addition to many others. Furthermore, a method for using the claimed apparatus would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 18, 19, 21, 22, 24, 25 and 31-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/972,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application contain all of the limitations of the current independent claims in

addition to many others. Furthermore, a method for using the claimed apparatus would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 18, 22, 32, 33, 35, 36, 43, 44, 46, 47 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Grandjean et al. (US 5,009,229, hereinafter Grandjean). Grandjean discloses an apparatus capable of being inserted into and stimulating muscle tissue, of which the myocardium of the heart would be included (see abstract). The apparatus has an anchor 122 for abutting a surface of a muscle, as well as a tension element 120 attached to the anchor (see figures 2, 3 and 6, Col. 3, lines 44-48). The tension element extends from the proximal end of the lead and completely through the pole 114 of electrode 100, which forms an inner guide channel due to its coil (See figure 4 and Col. 3, lines 32-36 and 58-62). Furthermore, the tension element has a “proximal end” that is considered to be the entire length of the element extending from the anchor 122 to connector 102, while the “distal end” of the tension element can be considered the entire length of the element extending from the anchor to the needle 118. Therefore, since the distal end of the lead 100, electrode portion 114, is not

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connected to the tension element, it allows for some slideable movement along the “proximal end” (as defined above) of the tension element both towards and away from the anchor during implantation. Furthermore, the proximal end of the lead 100 is coupled to the tension element (Col. 3, lines 32-34).

13. Since the tension element is not attached to the electrode, the electrode is inherently allowed to slide over the tension element.

14. Regarding claim 22, the anchor 122 expands from a straightened strand to an expanded coil when deployed in the operating condition, as described in Peters, US 4,341,226, incorporated by reference into Grandjean (Col. 3, lines 45-48).

15. Regarding claims 33, 35 and 46, the tension element is “attachable to” the electrode by pulling the tension element through one of the coils of the electrode, which would then act as a fastening element (see figure 4).

16. Regarding claims 36 and 47, as shown in figure 6, the electrode 114 acts as a stop since it is not permitted to move forward once it makes contact with the muscle.

17. Regarding claim 44, tool 118 is detachably coupled to the anchor (see Peters, US 4,341,226, incorporated by reference into Grandjean).

18. The applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims 38 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandjean in view of Official Notice. Grandjean, as described above, discloses the applicant's basic invention with the exception of the electrode including an anode spaced apart from a cathode. However, the use of unipolar and bipolar electrodes and pacing is notoriously old and well known in the art as being interchangeable configurations for stimulating muscle tissue. One of ordinary skill in the art would have found it obvious to modify the pole to include both an anode and a cathode to allow for bipolar pacing, especially since this allows for charge balancing, which results in less pain felt by the patient.

22. Claims 39, 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandjean in view of Wesbey et al. (US 3,244,174, hereinafter Wesbey).

Grandjean, as described above, discloses the applicant's basic invention with the exception of having two electrodes branching from a common supply lead for stimulating the heart. Attention is directed to the secondary reference of Wesbey, which discloses a system for implanting multiple conductors in a heart by inserting two conductors 24 extending from a common supply lead into the myocardium of the heart, as shown in figure 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Grandjean by utilizing two leads extending from a common supply as taught by Wesbey in order to stimulate two locations of a muscle at the same time.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Friday from 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. D. B./
Examiner, Art Unit 3766

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
July 6, 2008